

Application Serial No. 09/555,459
Amendment dated 16 September 2005
Reply to Office Action mailed 16 May 2005

REMARKS

Reconsideration and allowance in view of the following amendments and remarks are requested.

Claims 1-10 are pending in the present application. By this Amendment, Applicants have amended claims 1, 5, and 10. Support for the amendments can be found in the specification and claims as originally filed. Specifically, support can be found, *inter alia*, at page 8, line 20, and page 9, lines 9-10. The amendments introduce no new matter, and thus, their entry is respectfully requested.

This Amendment follows a personal interview held July 28, 2005 between Applicants' attorney, Steven M. Giovannetti, and Examiner Sharmila S. Gollamudi. The courtesies extended Applicants' attorney during the Examiner interview are sincerely appreciated. The Remarks presented in this Amendment make of record and further address the issues discussed during the interview.

Claim Rejections - 35 U.S.C. § 112 - second paragraph

The Examiner has rejected claims 5 and 9 under 35 U.S.C. § 112, second paragraph, as being indefinite. The Examiner has objected to the use of the phrase "further consisting." In accordance with the Examiner's suggestion, Applicants have amended Claim 5 to recite, "a sachet consisting of a polyethylene-aluminum foil laminate, a polyester outer layer, and a plastic rib-and-groove reclosing means ..." Accordingly, Applicants submit that claims 5 and 9 satisfy the requirements of 35 U.S.C. 112, second paragraph. Thus, withdrawal of this rejection is requested.

Applicants note that Claim 10 has also been amended in a manner consistent with Claim 5 for purposes of consistency.

Application Serial No. 09/555,459
Amendment dated 16 September 2005
Reply to Office Action mailed 16 May 2005

Claim Rejections - 35 U.S.C. § 103(a)

The Examiner has rejected claims 1-3, 6 and 8 under 35 U.S.C. § 103(a) as being obvious over Groenewegen et al. (U.S. 6,544,546) in view of FR 2748994. The Examiner contends that Groenewegen et al. disclose a package for a vaginal ring having all three layers in accordance with the present claims. The Examiner concedes, however, that Groenewegen et al. do not teach a reclosable package where the package has a reclosable strip comprising a strip of polymeric material which prevents the active substances present in the ring from leaking to the environment. The Examiner contends that FR 2748994 cures the deficiencies of Groenewegen et al. by teaching a package for disposing of used condoms having a flap that can be resealed. The Examiner contends that it would have been obvious to apply the flap of FR 2748994 to the package of Groenewegen et al. to arrive at the claimed invention because FR 2748994 teaches a package that can be resealed which allows for hygienic disposal of contraceptive devices. Set out below is a summary of the arguments and points of distinction presented and discussed at the Examiner interview including additional arguments distinguishing the present invention over the cited art.

To make out a *prima facie* case of obviousness against a claim, the Office is required to make a showing as to all three of the following: (1) the cited references must teach or suggest all elements of the rejected claim; (2) there must be a motivation to combine or modify the teachings of the cited art to arrive at the claimed invention; and (3) there must be a reasonable expectation of success for the combined art. MPEP. §2143. Motivation to combine or modify can come from the teaching of the prior art, the knowledge of person's of ordinary skill in the art, or the nature of the problem solved by the claimed invention. See MPEP §2143.01. Failure to meet only one of these standards is fatal to a showing of *prima facie* obviousness.

Applicants first submit that the combined cited art does not teach or suggest all of the elements of the present claims. As thoroughly discussed in the interview, Groenewegen et al. do not teach an aseptic package having a reclosable strip, wherein the package prevents the active substances present in a medicated intravaginal ring from leaking to the environment according to

Application Serial No. 09/555,459
Amendment dated 16 September 2005
Reply to Office Action mailed 16 May 2005

the claimed invention. Further, FR 2748994 does not correct this deficiency. Indeed, FR 2748994 describes a package for disposal of a used condom. The closing means provided in FR 2748994 is not a reclosable strip according to the claimed invention. In fact, the closing means as described in FR 2748994 is a closing flap and can only be closed once (this is indicated in French at page 3, line 4, “*le cellage definitif*”). Moreover, nothing in FR 2748994 suggests or indicates that the sealable flap described therein is constructed in a manner that would prevent active substances present in a medicated intravaginal ring from leaking to the environment. Accordingly, the cited art does not teach all of the elements of the claimed invention.

Applicants also submit that there is no motivation to combine the teachings of Groenewegen et al. and FR 2748994. Before prior art references can be combined or modified, there must be some suggestion or motivation found in the art to make the combination or modification. *In re Dance*, 160 F.3d 1339, 1343 (Fed. Cir. 1998). The fact that references can be modified or combined is insufficient to meet this criterion. *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1990). Groenewegen et al. merely discloses a package for packing a ring shaped device, but it does not provide any suggestion or motivation to modify such package so that it can be reused, i.e., opened and re-closed by means of a reclosable strip, and still prevent leakage of active substances to the environment. Furthermore, FR 2748994 teaches a package for disposing used condoms, however, the package has a flap with an adhesive that can be sealed once. The package is concerned with sealing contents for disposal, not reopening and reclosing, and there is no suggestion or teaching that such flap is reclosable or that it could prevent leakage to the environment of active substances present in a medicated intravaginal ring. The package in FR 2748994 is used once and then thrown away and is not concerned with leakage since it is disposed of rather than reused for storage and the like. Absent impermissible hindsight relying on the teachings in the present specification, there is no suggestion to modify and combine the features of the package of FR 2748994, which has a flap that is sealed once, with the package disclosed in Groenewegen et al. to create a aseptic package according to the claimed invention which has a reclosable strip and prevents the active substances present in a medicated

Application Serial No. 09/555,459
Amendment dated 16 September 2005
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intravaginal ring from leaking to the environment. Furthermore, even if the teachings of the above references were combined, the resulting package would not meet the terms of the claimed invention and one would instead arrive at a sachet with a flap that could only be sealed once (i.e., it could not be reused) and which would not prevent the active substances present in a medicated intravaginal ring from leaking to the environment .

In light of the above remarks, it is submitted that claims 1-3, 6 and 8 are not obvious over Groenewegen et al. in view of FR 2748994. Withdrawal of this rejection is requested.

The Examiner has also rejected claims 1-5 and 7-10 under 35 U.S.C. § 103(a) as being obvious over Groenewegen et al. (U.S. 6,544,546) in view of JP 7-223653.

The Examiner again describes the teachings of Groenewegen et al. as discussed above and also concedes that Groenewegen et al. do not teach a reclosable strip, much less a rib-and-groove reclosing means. The Examiner contends that JP 7-223653 cures the deficiencies of Groenewegen et al. by teaching a package having a sliding clasp fastener that can be utilized for medical products. The Examiner contends that the package in JP 7-223653 provides air tightness and stability to the package contents and therefore, it would have been obvious to combine the teachings of JP 7-223653 and Groenewegen et al. to arrive at the claimed invention.

Applicants submit that the combined cited art do not teach or suggest all of the elements of the present claims, nor is there any motivation or suggestion provided to combine the teaching of the cited art to arrive at the claimed invention. The Examiner contends that the JP 7-223653 bag prevents leakage of the contents contained therein, and the Examiner indicated at the interview that this assertion was based on the teachings in JP 7-223653 that the bag prevents evaporation and odour leakage. Applicants maintain, however, that JP 7-223653 relates to a packing bag comprising a laminated body with a zip (the term used in the translation) having at least 4 layers for, e.g., food products, cosmetics and medical products such as compresses and ointments. JP 7-223653 does not, however, relate to intravaginal rings, let alone intravaginal rings comprising active ingredients. JP 7-223653 also does not relate to the problem of leakage of active substances from such a ring into the environment. It relates to a different problem,

Application Serial No. 09/555,459
Amendment dated 16 September 2005
Reply to Office Action mailed 16 May 2005

namely to provide air tightness so that the contents of a bag do not dry out, evaporate, moisturize, degenerate, volatilize or leak odour (see page 5 of the enclosed translation). As such, it does not teach a package having a reclosable strip or rib-and-groove reclosing means according to the claimed invention, which prevents the active substances present in a medicated intravaginal ring enclosed therein from leaking to the environment. Thus, all of the elements of the claimed invention are not disclosed in JP 7-223653 and Groenewegen et al.

Furthermore, there is no suggestion or motivation to combine the zip package of JP 7-223653, which is suitable for packaging compresses and ointments (not, e.g., hormone-containing ring devices), with the three layered package of Groenewegen et al., which is used for ring devices but is not reclosable. Absent impermissible hindsight relying on the teachings in the present application, a person of skill in the art would not be motivated to modify or combine the closing feature of JP 7-223653 with the package of Groenewegen et al. in an attempt to create a reclosable aseptic package that prevents the active substances present in a medicated intravaginal ring stored therein from leaking to the environment. Moreover, since there is no teaching or suggestion of a reclosable strip or rib-and-groove reclosing means that can prevent active substances present in a medicated intravaginal ring from leaking to the environment, one would not arrive at the claimed invention even if the teachings of the above references were combined.

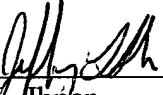
The above arguments notwithstanding, Applicants have amended claims 1, 5 and 10 in accordance with proposed amendments discussed during the Examiner interview, in order to expedite prosecution. Applicants have specified that the reclosable strip comprises either a low-density polyethylene or a high-density polyethylene. There is no teaching in the cited art of a package according to the claimed invention, having a reclosable strip comprising a low-density polyethylene or a high-density polyethylene. JP 7-223653 does not specify the material that the zip is made of, much less teach the specific material in accordance with the claimed invention.

In view of the above remarks and amendments, it is submitted that the present claims are not obvious over Groenewegen et al. in view of FR 2748994 or JP 7223653. Withdrawal of this rejection is requested.

Application Serial No. 09/555,459
Amendment dated 16 September 2005
Reply to Office Action mailed 16 May 2005

In view of the above amendments and remarks, and the substance of the personal interview conducted July 28, 2005, it is believed that the claims satisfy the requirements of the patent statutes and are patentable over the prior art. Reconsideration of the instant application and early notice of allowance are requested. The Examiner is invited to telephone the undersigned if it is deemed to expedite allowance of the application.

Respectfully submitted,
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Enclosure: Japanese Patent No. 7-223653
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